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(54) Title: SURGICAL PROCEDURES AND INSTRUMENTS

(57) Abstract: Surgical instruments and methods are provided. In one aspect, a method of securing a fixation device within an opening in a tissue is provided, including delivering a material in a flowable state to said opening, and changing the state of the material so that the material forms an interference fit that secures the fixation device in the opening.

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implementations, bone fragments are incorporated into the flowable material as an autologous filler, to enhance regrowth of bone into the material during natural healing.

Using preferred surgical procedures and instruments of the invention, fixation can be performed endoscopically, rather than in an open surgical procedure, resulting in less invasive treatment with minimal trauma to the patient. In preferred implementations piercing of soft tissue, drilling of a cavity, delivery of a suture and/or bone anchor (if used), and injection of the flowable material into the cavity are performed using a single endoscopic surgical instrument. In some preferred implementations knot-tying, which tends to require considerable skill and dexterity and is generally time-consuming, is not necessary. Thus, the surgical procedures of the invention are generally relatively quick, reducing trauma, and relatively easy to perform. In some implementations, the methods of the invention allow a series of connected, tensioned stitches to be made to fix a region of soft tissue to bone.

In implementations in which a conventional bone anchor is not used with the flowable material, certain risks that may be associated with such bone anchors are eliminated. For example, if a suture is used the suture does not run through an eyelet, and thus will not be microscopically damaged by friction between the suture and eyelet. Also, anchors formed using a flowable material do not rely heavily on the quality and density of the bone in which the anchor is placed, and thus a placement in compromised, low density bone may still exhibit good holding power.

The invention also features surgical procedures involving endoscopic application of polymers for other purposes, e.g., to repair a bone defect, to fill holes that are left when bone plugs are harvested, to repair osteochondritis dessicans injuries, for repair or revision of ACL grafts that exhibit micromovement, for spine fusion, for meniscal repair, and to repair bone fractures. The use of endoscopic devices and techniques significantly reduces

into the material during or prior to the delivering step. The method further includes causing the material to infiltrate the trabecular network. The material includes an osteoconductive filler. The opening is formed using micro-tooling. The opening has a diameter of less than about 3 mm. The forming step includes forming the opening using a consumable cutting tool, and the delivering step includes causing the cutting tool to melt in response to frictional heat generated during the forming step. The forming step includes forming the opening with a cutting tool having a detachable portion, and the method further includes detaching the detachable portion in the opening after the forming step is completed, to serve as the fixation device.

In another aspect, the invention features a method of anchoring soft tissue to bone including (a) piercing the soft tissue; (b) forming an opening in an underlying area of the bone; (c) delivering a material, in a flowable state, to the opening; and (d) molding a portion of the material that is not in the opening to form a fixation device constructed to hold the soft tissue in place against the bone after the material changes state to a relatively less flowable state.

Implementations of this aspect of the invention may include one or more of the following features. The molding step includes forming a portion of the material into a shape that extends radially over a portion of the soft tissue surrounding the opening. The forming step includes drilling or abrading. All of the steps are performed endoscopically. The method further includes incorporating bone fragments generated during the forming step into the material during or prior to the delivering step. The material includes an osteoconductive filler. The method further includes causing the material to infiltrate the trabecular network The opening has a diameter of less than about 3 mm, more preferably from about 0.1 to 6.0 mm. The forming step is performed using micro-tooling. The material includes a polymer. The formed portion extending

forming step includes drilling or abrading. The forming step is performed using micro-tooling. The forming step is performed in the bone of a human shoulder.

In yet another aspect, the invention features a surgical instrument for tissue fixation including (a) a handpiece constructed to be held by a surgeon during a fixation procedure; and (b) a fixation instrument, mounted on the handpiece and including (i) a piercing element constructed to pierce through the tissue and form an opening therein; and (ii) a lumen for delivery of a material, in a flowable state, and a fixation device to the opening.

Implementations of this aspect of the invention may include one or more of the following features. The fixation device includes a suture. The surgical instrument further includes a suture feed mechanism constructed to deliver the suture through the lumen to the opening. The surgical instrument is constructed for endoscopic use. The surgical instrument further includes a heating element for heating the material to a molten state. The heating element is mounted on the fixation instrument. The suture feed mechanism includes a movable needle. The surgical instrument further includes a probe constructed to tighten a stitch formed with the suture, e.g., mounted on an external surface of the fixation instrument. The probe is constructed to be manually actuated by a surgeon during an endoscopic procedure. The handpiece includes a reservoir for receiving the material in solid form. The reservoir is constructed to receive a supply of pellets of the material and the handpiece further comprises a mechanism for delivering the pellets from the reservoir to the lumen. Alternatively, the reservoir is constructed to receive a supply of powdered material and the handpiece further comprises a mechanism for delivering a predetermined dose of powdered material from the reservoir to the lumen. The fixation instrument is detachable from the handpiece. The surgical instrument further includes a mixing device constructed to mix bone fragments and debris generated during opening forming into the material prior to

member; and (d) forming each of the softened extending portions so that each extends radially over a portion of the soft tissue to secure the two layers of soft tissue together.

In some implementations, the member includes a hollow tube and the forming step results in a rivet-like anchor.

In another aspect, the invention features a method of securing two tissues together including (a) forming an opening extending through the two tissues, (b) delivering a material, in a flowable state, to the opening, and (c) causing the material to change state, to a relatively less flowable state; wherein the material forms an anchor that secures the two tissues together. In some implementations, the anchor is a bolt-like anchor.

In a further aspect, the invention features an endoscopic instrument for securing two tissues together including (a) a piercing device constructed to form an opening extending through the two tissues; and (b) a delivery device constructed to deliver a material, in a flowable state, and a fixation device, to the opening.

In another aspect, the invention features surgical instruments constructed to perform the steps of the methods described above. Preferred instruments are constructed to perform all steps of the methods endoscopically.

Other features and advantages of the invention will be apparent from the description and drawings, and from the claims.

DESCRIPTION OF DRAWINGS

Fig. 1 is a diagrammatic perspective view of the surgical environment of an endoscopic procedure according to one embodiment of the invention.

Figs. 2-2K are diagrammatic views of a procedure for forming a series of polymeric anchors connected by stitching.

Figs. 3-3E are views of a surgical instrument suitable for performing the method shown in Figs. 2-2K. Fig. 3 is a side view of the surgical instrument. Fig. 3A is a highly enlarged detail perspective view of

Figs. 16 and 16A are perspective and side views, respectively, of an alternative cutting tool.

Figs. 17 and 17A are perspective views of an alternative cutting tool in closed and open positions, respectively.

Figs. 18 and 18A are perspective and front views, respectively, of an alternative cutting tool.

Fig. 19 is a perspective view of an alternative cutting tool.

Figs. 20 and 20A are perspective and cross-sectional views, respectively, of an alternative cutting tool. Fig. 20B is a diagrammatic cross-sectional view showing the cutting tool of Figs. 20-20A in use.

Figs. 21-21G are diagrammatic views of various types of augmented sutures.

DETAILED DESCRIPTION

Referring to Fig. 1, a surgical site 10 includes a number of portals 12, through which endoscopic devices can be inserted. The surgeon can view the surgical site using an arthroscope 14, while placing a polymeric anchor, as will be discussed in detail below, using a surgical instrument 16. Surgical instrument 16 generally depicts an instrument for placing a polymeric anchor. Examples of particular instruments that are suitable for use in the various methods of the invention will be discussed in further detail below. In the initial step shown in Fig. 1, the surgeon is using a shaver 18 to remove a portion of soft tissue 20, expose the surface 24 of bone 22 and create a bleeding bone bed, in preparation for the surgical procedures described below. While shaver 18 is shown as a separate instrument in Fig. 1, it may instead be integrated with surgical instrument 16.

A procedure for fixing soft tissue to bone is shown in Figs. 2-2K. In this procedure, one or more stitches are formed to fix the soft tissue to the bone over an area. The steps shown in Figs. 2-2K are performed endoscopically, in the environment shown in Fig. 1.

After the suture is positioned, needle 72 is retracted and molten polymer 28 is injected into the cavity around suture 70 (Fig. 2C). The polymer 28 penetrates through the side walls and bottom of the cavity into the trabecular network (cancelous bone) in region 30.

Once polymer 28 has at least partially solidified, anchoring the suture in the cavity, the surgical instrument 16 is retracted (Fig. 2D), and suture 70 is fed from the surgical instrument as the surgical instrument is moved to a second location (Fig. 2E). As shown in Fig. 3A, and discussed in further detail below, as the suture 70 is fed from the instrument it exits the instrument through an inverted-L-shaped channel 69 extending up the side 74 of the surgical instrument, so that the suture is not cut during the piercing of the soft tissue.

When the surgical instrument is positioned at the second location, the surgical instrument again holds the soft tissue 20 in place, and cutting tool 26 again pierces the soft tissue 20 (Fig. 2E). The cutting tool 26 is then reciprocally oscillated to form a second cavity, as shown in Fig. 2F. (At this stage, the cutting tool cannot be rotated 360 degrees, as this would cut or break the suture, or cause the suture to wind around the cutting tool. Thus, the surgeon sets the programmable drive mechanism to an oscillating mode. The surgeon can use either a rotating or an oscillating motion to form the first cavity (Fig. 2A), depending on the surgeon's preference.) The suture 70 is fed from the supply reel into the new cavity, and positioned by advancing needle 72 into the cavity, as shown in Fig. 2G (as discussed above, the suture could instead be positioned by gravity).

A probe 71 is used to press the suture through the soft tissue, compressing the soft tissue against the surface of the bone in the vicinity of the second cavity and tensioning the suture material as it passes between the cavities, tightening the "stitch" that will be formed between the cavities. Needle 72 is retracted, leaving a loop

from Smith & Nephew, Andover, MA, under the tradename DYONICS™.

Referring to Fig. 3, handpiece 52 is constructed to be held by a surgeon during a surgical procedure, and includes switches 56a, 56b and 56c that are positioned to be easily actuated by the surgeon to control the functions of the surgical instrument, as will be discussed below. Handpiece 52 is connected to a power supply by an adapter cord 39 (e.g., a Dyonics EP1 power supply cord, available from Smith & Nephew). The handpiece 52 may be fitted with interchangeable molded grips, e.g., two-piece housings that snap on over the handpiece 52 and include recesses through which switches 56 extend, thus providing the surgeon with a more customized grip.

Referring now to Figs. 3B and 3C, the handpiece 52 includes a removable polymer cartridge 40 that is preloaded with a supply of polymer pellets 45 (Fig. 3E) prior to surgery, and a chamber 41 (Fig. 3C) for receiving the polymer cartridge. The polymer cartridge 40 includes aligned slots 42a, 42b, through which a pellet can be pushed out for delivery to a cavity.

To push a pellet out of the cartridge for delivery, the surgeon pulls back on switch 56a. This causes toothed cam 57 to push rod 58 against inclined surface 59 of block 60, causing block 60 to move downward through slot 42a, thereby displacing the pellet through slot 42b into chamber 43 through an cavity that is not shown in the cross-section of Fig. 3B. The pellet then passes into the lumen of the attachment 54 through an cavity 44 (Fig. 3D). After the pellet has been dispensed, block 60 is returned to, and biased in, its previous position by spring 61. This reverses the movement of the rod 58 and toothed cam 57, returning the switch 56a to its normal position. The pellets are advanced toward the proximal end of the cartridge, to move a new pellet into place for delivery through slot 42b, by spring 47 (Fig. 3E).

When the piercing/cavity forming function is selected, i.e., when switch 56c is moved to the right in Fig. 3B, a spline (not shown) in the center of cog 150 engages end 152 of drive shaft 154 of the motor. Simultaneously, the teeth of cog 150 engage the teeth of cog 156, causing shaft 158 to rotate, driving bevel gear 160 which engages bevel gear 162 on the cutting tube 164 of attachment 54. Engagement of bevel gears 160 and 162 rotates the cutting device 176 (or oscillates the cutting device, depending on the setting of the programmable drive). The motor is programmed to stop rotation, when the piercing/cavity forming function is deselected, in a position in which cavity 44 is aligned with the polymer-delivery cavity in the handpiece that is in turn aligned with cavity 42b of the polymer cartridge.

Referring to Fig. 3D, the attachment 54 includes an inner cutting device 176 that slides into an outer guide/heating device 178 when the surgical instrument is assembled for use. When the instrument is assembled, as shown in Fig. 3C, the guide/heating device 178 snaps into the handpiece 52, and the cutting device 176 is trapped between the handpiece 52 and the guide/heating device 174.

Cutting device 176 includes a cannulated cutting tube 164 having a cutting tip 180, a member 182 that defines chamber 43 and a gas inlet 184, and bevel gear 162. End 181 of the cutting tube includes a flap valve 183 to prevent the compressed gas from escaping through end 181. When the suture delivery function is selected, the pressure of the end of the advancing suture opens valve 183, and the suture is guided through the cavity at end 181 by a conical portion 185.

Guide/heating device 174 includes a cannulated guide tube 186 and, within the guide tube, a heating element 188 for melting the polymer pellets. The guide tube 186 includes a movable probe portion 71, which can be moved axially (arrows C, Figs. 3 and 3A) by the surgeon, using grip 190, to push the suture 172 against the soft

function, deliver a desired amount of suture to the cavity, move switch 56c to deactivate the drive motor, lower probe portion 71 to tighten the "stitch" between the cavities, and move switches 56a and 56b to deliver polymer to the cavity. These steps would be repeated to form as many stitches as desired.

If desired, the surgical instrument may be used to deliver polymer without performing any cutting procedure.

An alternative procedure for forming a row of stitches is shown in Figs. 4-4G. In this procedure, the bone fragments and debris generated during cavity forming are incorporated into the polymer as a filler. It is noted that bone fragments and debris can be incorporated into the polymer in a similar manner in any of the procedures described herein. The procedure shown in Figs. 4-4G is performed using a surgical device 116 that is similar to surgical device 16, except that it also includes a suction device for extracting bone fragments and debris from the cavity, and a mixing chamber and a mixing device, for incorporating the bone fragments and debris into the polymer.

Referring to Figs. 4 and 4A, using surgical instrument 116 the soft tissue 20 is pierced and a cavity is drilled in the bone 22, as discussed above. In this embodiment, the cutting tool is a perforated drill 80 (similar to a grater), having a serrated tip 82. Because the drill tip is serrated, it is preferred that the surgical instrument 116 be held at an angle, rather than perpendicular to the surface of the soft tissue 20, as indicated by angle A in Fig. 4, until the soft tissue 20 has been pierced. During drilling, the resulting bone fragments and debris 84 are suctioned out of the cavity and up through the cannula of the drill, as indicated schematically in Fig. 4B. The bone fragments/debris are then retained in a temporary chamber 86, defined by the cylindrical cutting tool barrel and a balloon diaphragm 88, suspended on a needle 90, that is inflated at this point in the procedure (arrows A, Fig. 4C). As shown in Fig. 4D, the surgeon then delivers suture 70 through needle 90, while simultaneously

Next, a compounder 34 (a part of surgical instrument 16 that has been retracted in previous steps) is extended (arrow A, Fig. 5C) so that the tip 36 of the compounder presses against soft tissue 20 to hold it against bone surface 24. Meanwhile, the cannulated head 32 of the surgical instrument 16, through which the polymer is delivered, is retracted a short distance so that, with the cylindrical wall of the compounder, it defines a small molding chamber. Polymer continues to be delivered through the cannula of the surgical instrument and this polymer fills the molding chamber to form a polymeric "bolt head" 38 (Fig. 5D). The bolt head 38 is integral with the polymer in the cavity, which extends through the soft tissue 20. Thus, the polymer forms a bolt-like anchor that secures the soft tissue to the bone (Figs. 5E and 5F).

As shown in Figs. 5E and 5F, the procedure is completed by removing the surgical instrument 16 (arrow A, Fig. 5E) and snipping any excess polymer off at the top of the bolt head. The manner in which the polymer is snipped off is not shown; if this step is necessary, it can be performed using a clipper attachment to the surgical instrument 16, or using a separate device such as a scalpel. The procedure shown in Figs. 5-5F can be performed using an attachment 225, shown in Fig. 6, mounted on the handpiece 52 that is shown in Figs. 3-3D and discussed above. The handpiece 52 can be used with a wide variety of interchangeable attachments, suitable for use in various procedures of the invention. For example, as shown in Fig. 7, the handpiece can be used with attachment 54 to perform a stitching procedure, with attachment 225 to form a bolt-like polymeric anchor using the procedure shown in Figs. 5-5F, and with attachments 250 and 300 to perform soft tissue to soft tissue fixation procedures that will be described below.

Attachment 225 is similar to attachment 54, discussed above, except that it does not include a chamber or cavity for receiving a polymer pellet. Instead, a polymer rod 226 (Fig. 6A) is advanced through the handpiece using the suture delivery function. The

out of tip openings 256. The hot air melts the polymeric sheath, and the cold air forces it downward (arrows D, Fig. 8B) against the soft tissue (Fig. 8D). The hot air is generated at the tip due to the relationship between the air pressure being forced out of the tip and the size of side openings 254.

The inner tube 253 of instrument 250 is then withdrawn through the polymeric sheath until the side openings 254 are aligned with portion 252b of the polymeric sheath (Fig. 8C). Hot air is directed out through the side openings 254 (arrows H, Fig. 8D) to melt portion 252b. Flange 260 of compounder 259 is then pressed against portion 252b, while cold air is directed out through tip openings 256 (Fig. 8E), solidifying portion 252b in place against the soft tissue (Fig. 8F). The air is directed by flange 260, which also serves to press portion 252B against the soft tissue. The surgical instrument 316 is then withdrawn (Fig. 8F), leaving a rivet-like anchor 262 (Fig. 8G) to hold the soft tissue firmly together.

A surgical instrument attachment 250, for use with handpiece 52 to form a surgical instrument 316 suitable for performing the procedure shown in Figs. 8-8F and described above, is shown in Fig. 9. Attachment 250 includes the components described above with reference to Figs. 8-8F, and can be mounted on handpiece 52 in the same manner as attachment 54, discussed above.

An alternative procedure for fixing soft tissue to soft tissue is shown in Figs. 10-10H. This procedure is performed using a surgical instrument 416, which generally includes an inner tube having a sharp tip for piercing soft tissue and a cannulation for delivery of polymer. The surgical instrument 416 also includes a device for releasably mounting a porous sheath over the inner tube. First, the soft tissue is compressed and is pierced by the sharp tip of surgical device 416 (Figs. 10, 10A), as described above with reference to Figs. 8 and 8A. The distal end 306 of a porous sheath 302, e.g, a braid or mesh, is gripped by a releasable chuck 304. A small polymer weld (not shown) near distal end 306 of the sheath

constructed to leave a bone core 330 in the cavity (Fig. 12C). A flexible sleeve 332, e.g., a braided hollow suture, is deployed over the core 330, as shown in Fig. 12C. Polymer 28 is then delivered to the cavity (Figs. 12D, 12E) around the sleeve 332 and core 330, and impregnates the sleeve 332. More polymer is delivered, while retracting the surgical instrument (Figs. 12F, 12G), to form a blob 334 on the surface of the soft tissue, anchoring the soft tissue against the bone (Fig. 12H). Any excess sleeve material is then snipped off (Fig. 12I). The presence of the bone core in the anchor will tend to increase bone remodeling, and thus the suture may become embedded in bone more rapidly than would occur if the bone core were not present.

Another alternative soft tissue to bone fixation procedure is shown in Figs. 13-13J. In this procedure, a suture is anchored in a cavity, using polymer, and a fixation device 340 is deployed around, and adhered to, the suture above the soft tissue to mechanically clamp the soft tissue in place. This procedure provides a low-profile anchor that may be useful in low clearance areas to prevent impingement. This procedure is performed using a surgical instrument 616 that includes a cutting tool to pierce soft tissue and form a cavity in underlying bone, a cannulated tube for delivery of a suture and polymer to the cavity and deployment of a fixation device around the suture, and a compounder to press the soft tissue against the bone and the fixation device against the soft tissue. As shown in Figs. 13-13C, soft tissue is pierced, a cavity is formed, and suture and polymer are delivered as discussed above, e.g., with regard to the procedures shown in Figs. 2-2K. Next, while holding down the soft tissue with a compounder 335 (Fig. 13D), an expandable fixation device 340 is deployed around the suture to clamp the soft tissue in place (Figs. 13E-13G). The expandable fixation device 340 includes a central region 341, having a bore 346, and a plurality of wings 354 extending radially from the central region. Wings 354 are joined to central region 341 by a plastic hinge

The ceramic can be applied by firing, plasma coating, deposition, or other suitable methods. Alternatively, a thin, hollow ceramic preform can be formed and then filled with polymer. Preferred polymers have a sufficiently low melting point to melt under drilling friction, and sufficient strength to contribute mechanical strength to the drill bit. The suture 95 may be conductive, to allow it to serve as a heating element to assist in melting the polymer if drilling does not generate sufficient heat.

Figs. 15-20 show various suitable cutting tool geometries. Figs. 15 and 15A show a perforated drill 100, including openings 96 and sheath 98. Perforated drill 100 is useful when bone fragments/debris are to be collected for incorporation into the polymer (as discussed above with reference to Figs. 4-4J), and when it is necessary that the cutting tool oscillate, rather than rotating (e.g., to avoid cutting or breaking a suture between stitches). Figs. 16-16A show a configured head 102, having a blade 103 that includes an opening 104 through which a suture can be threaded for delivery, and a barrel 105 defining a lumen 106 for suture and polymer delivery. Lumen 106 is generally substantially coaxial with opening 104.

Figs. 17-17A show an awl 110. Awl 110 includes a plurality of retractable "petals" 112, which when closed (as shown in Fig. 17) define a drill tip. When open (as shown in Fig. 17A), the petals 112 allow polymer and suture to be delivered through lumen 114. The petals may be opened and closed using a spring mechanism (not shown) or other suitable actuator.

Figs. 18-18A show a cutting head 120 having blades 122 radially extending cross-wise across an open lumen 124. An open area between the blade tips defines an eyelet 126, to allow delivery of a knotted suture.

Fig. 19 shows a borer 126, including a plurality of serrated cutting/abrading tubes 128, a central lumen 130 through which polymer and suture can be delivered, and an extraction tube 132 for

may be contained in a cartridge that can be heated using equipment that is available in the operating room, e.g., an autoclave or heated bath. Thus, the cartridge can be preheated prior to surgery, and then inserted into a surgical instrument (not shown) that is adapted to puncture the cartridge for delivery of the polymer. The polymer may also be provided as a rod, or in the form of fibers or strands to increase its surface area and thereby decrease melting time.

The polymer can be heated using any suitable method. Preferred methods will heat the polymer in a controlled manner, to a temperature just above its melting temperature, to avoid overheating and possible thermal trauma to the tissue and bone at the delivery site. To expedite the surgical procedure, it is preferred that heating occur within 2 minutes or less, unless the polymer is provided in a cartridge and is pre-heated, e.g., in an autoclave. One suitable method is to provide a heating element in the surgical instrument, as discussed above. Preferably the heating element is thermostatically controlled to prevent overheating of the polymer. Other suitable heating methods include ultrasound (which may also be used to form the cavity), use of the drive mechanism of the surgical instrument to heat the polymer, use of a conductive suture embedded in the polymer as a heating filament, laser (e.g., by including an indicator dye in the polymer and using a laser frequency that would not burn the tissue at the delivery site but would melt the polymer), and radio frequency and induction heating.

The suture material, if a suture is used, may be resorbable or non-resorbable. It is generally preferred that the suture material be braided, rather than monofilamentary, for greater surface area and surface roughness, to enhance pull-out strength. However, monofilament may be used if desired. A loose braid is generally preferred, as the spaces in the braid enhance polymer infiltration. A "bird's nest" arrangement of suture can also be formed by feeding suture out into the cavity and allowing it to pile up loosely in the cavity. Preferably, the suture does not include a polymeric coating.

polyurethane. The polymer may also include a blend of different resorbable polymers that resorb at different rates, e.g., blends of two or more of the following polymers: polycaprolactone (PCL), poly-l-lactic acid, poly-DL-lactic acid, polyglycolic acid, polydioxanone, polyglyconate, polytrimethylene carbonate, and copolymers of poly-L-lactic acid, poly-DL-lactic acid, polyglycolic acid, polydioxanone, polyglyconate, polytrimethylene carbonate, poly(hydroxyalkonates) (PHB, PHO, PHV), polyorthoesters, polyanhydrides, poly(pseudo-amino acids), poly(cyanoacrylates), poly(ester-anhydrides), polyoxalates, and polysaccharides. Other suitable polymers include poly-4-hydroxybutyrate (4PHB) and poly(alkylene oxalates).

As the polymer resorbs, the remaining, porous polymer resembles the trabecular network and thus encourages infiltration of osteoclasts, which cause breakdown of the polymer, and osteoblasts, which generate new bone. To encourage bone growth into the polymer, it is preferred that the polymer include an osteoconductive filler, e.g., hydroxyapatites (HA), calcium sulfates, tricalcium phosphates, bioactive glasses, aragonite, calcite, and mixtures of these fillers. A suitable level of osteoconductive filler will encourage bone growth without an unacceptable reduction in the deliverability of the polymer. Preferred levels are generally from about 0 to 40% by volume, most preferably about 30 to 40% by volume. Instead of or in addition to a conventional osteoconductive filler, the polymer may include bone fragments and debris, as discussed above. If bone fragments are used without another filler, it is generally preferred that the polymer include from about 0 to 60% bone fragments by weight, more preferably about 20 to 50% by weight.

The procedures discussed above may be used in many types of soft tissue fixation, including rotator cuff repair; instability repairs of the shoulder (e.g., SLAP, Bankart lesions, labral reattachment); repair or supplementation of anchors, screws and interference screws for attaching ACL autografts and allografts (e.g., bone-patella

All of the shoulders used would be harvested from fresh specimens, i.e., unpreserved, and stored at approximately -10 degrees Celsius until necessary for testing. Before testing, the specimens would be allowed to thaw to room temperature before dissecting and sample preparation.

The humerus would be prepared for the repair of a rotator cuff tear at the bony site. A cavity would be drilled to a depth of about 10 mm using a twist drill bit having a diameter of 3.3 mm. A suture, e.g., Spectra thread or similar suture material, would be delivered to the cavity, and the cavity would be filled with polymer. The polymer would be allowed to harden/set, after which the sample would be placed in an Instron servo-hydraulic testing machine, with the suture orientated parallel in relationship to the force applied by the testing machine.

The samples would be held in an appropriate vice/clamp which is itself attached to a 3-axis vice to permit the precise orientation of the samples being tested, using an appropriate Instron servo-hydraulic testing machine and associated Instron Max software, at a displacement rate of 8.5 mm/sec.

Test Procedure 2: Sawbone Block Samples

Samples would be prepared and tested as described above in Test Procedure 1, except that instead of a cadaveric humerus, the anchor would be formed in a sawbone block. A suitable sawbone block material is commercially available from Pacific Research, under the tradename "Sawbones".

Other embodiments are within the claims.

For example, although in most of the embodiments discussed above polymer is used as a substitute for a conventional bone anchor, in some cases it may be desirable to use the polymer to supplement the anchoring provided by a conventional anchor, e.g., by applying the polymer on top of or around the anchor when the

CLAIMS

1. A method of securing a fixation device within an opening in a tissue, comprising:

delivering a material in a flowable state to said opening, and

changing the state of the material so that the material forms an interference fit that secures the fixation device in the opening.

2. The method of claim 1 wherein said tissue comprises bone.

3. The method of claim 1 wherein said tissue comprises soft tissue.

4. The method of claim 1 wherein said fixation device is selected from the group consisting of suture, anchors, and screws.

5. The method of claim 1 wherein the changing step comprises allowing the material to at least partially harden.

6. The method of claim 1 wherein the changing step comprises at least partially cross-linking the material.

7. The method of claim 1 wherein said material comprises a polymer.

8. The method of claim 7 wherein said polymer comprises a thermoplastic polymer.

9. The method of claim 1 wherein said material comprises a hydrogel.

10. The method of claim 1 further comprising using the fixation device to secure a second tissue to the tissue having the opening.

19. The method of claim 1 further comprising incorporating bone fragments into the flowable material during or prior to the delivering step.

20. The method of claim 1 wherein the flowable material includes an osteoconductive filler.

21. The method of claim 1 further comprising causing the flowable material to infiltrate the trabecular network

22. The method of claim 1 further comprising forming said opening.

23. The method of claim 22 wherein the forming step is performed using micro-tooling.

24. The method of claim 1 wherein the opening has a diameter of less than about 3 mm.

25. The method of claim 12 or 22 wherein the forming step comprises forming the opening using a consumable cutting tool, and the delivering step comprises causing the cutting tool to melt in response to frictional heat generated during the forming step.

26. The method of claim 12 or 22 wherein all of the steps are performed using a single endoscopic surgical tool having a plurality of attachments, and the tool is not removed from the patient until after the steps are completed.

27. The method of claim 22 wherein said forming step comprises forming the opening with a cutting tool having a detachable portion, and the method further comprises detaching the detachable portion in the opening after the forming step is completed, to serve as the fixation device.

36. The method of claim 28 wherein the opening has a diameter of from about 0.1 to 6.0 mm.

37. The method of claim 28 wherein the forming step is performed using micro-tooling.

38. The method of claim 28 wherein the material comprises a polymer.

39. The method of claim 29 wherein the formed portion extending radially over the soft tissue is coextensive with the material in the opening, defining a bolt-like anchor.

40. A method of fixing soft tissue to bone comprising:

(a) at a first location, piercing through the soft tissue;

(b) forming an opening in the bone underlying the soft tissue;

(c) delivering a fixation device through the pierced tissue to the opening;

(d) delivering a material, in a flowable state, to the opening; and

(e) causing the material to change state, to a relatively less flowable state, to anchor at least a portion of the fixation device in the opening.

41. The method of claim 40, wherein said fixation device is selected from the group consisting of suture, anchors and screws.

42. The method of claim 41 wherein said fixation device is a suture.

43. The method of claim 42, further comprising:

(f) drawing the suture across the soft tissue to a second location, and

53. The method of claim 40 further comprising incorporating bone fragments generated during the forming step into the material during or prior to the delivering step.

54. The method of claim 40 further comprising incorporating an osteoconductive filler into said material.

55. The method of claim 40 further comprising causing the material, in its flowable state, to infiltrate the trabecular network

56. The method of claim 40 wherein the forming step comprises forming a opening having a diameter of less than about 3 mm.

57. The method of claim 54 wherein the opening has a diameter of from about 0.1 to 6.0 mm.

58. The method of claim 40 wherein the forming step comprises drilling or abrading.

59. The method of claim 40 further comprising performing the forming step using micro-tooling.

60. The method of claim 40 wherein the method comprises performing the forming step in the bone of a human shoulder.

61. The method of claim 60 wherein the method comprises a rotator cuff repair.

62. A surgical instrument for tissue fixation comprising:

a handpiece constructed to be held by a surgeon during a fixation procedure; and

a fixation instrument, mounted on the handpiece and comprising

72. The surgical instrument of claim 62 wherein said handpiece comprises a reservoir for receiving the material in solid form.

73. The surgical instrument of claim 72 wherein said reservoir is constructed to receive a supply of pellets of the material and said handpiece further comprises a mechanism for delivering said pellets from said reservoir to said lumen.

74. The surgical instrument of claim 72 wherein said reservoir is constructed to receive a supply of powdered material and said handpiece further comprises a mechanism for delivering a predetermined dose of powdered material from said reservoir to said lumen.

75. The surgical instrument of claim 62, wherein said fixation instrument is detachable from said handpiece.

76. The surgical instrument of claim 62 further comprising a mixing device constructed to mix bone fragments and debris generated during opening forming into the material prior to delivery to the opening.

77. The surgical instrument of claim 62 further comprising a drive mechanism constructed to drive the piercing element.

78. The surgical instrument of claim 64 further comprising a drive mechanism constructed to drive the piercing element and the suture feed mechanism.

79. The surgical instrument of claim 77 or 78 wherein the drive mechanism is disposed in said handpiece.

88. A method of securing a first layer of soft tissue to a second layer of soft tissue comprising:

forming an opening extending through both layers of soft tissue;

delivering a material, in a flowable state, through the opening so that the flowable material extends beyond the soft tissue at each end of the opening; and

causing the material to change state, to a relatively less flowable state, forming an anchor to secure the two layers of soft tissue together.

89. A method of securing a first layer of soft tissue to a second layer of soft tissue comprising:

forming an opening extending through both layers of soft tissue;

delivering a thermoplastic member to the opening, so that a portion of the member extends beyond the soft tissue at each end of the opening;

softening the extending portions of the member; and

forming each of the softened extending portions so that each extends radially over a portion of the soft tissue to secure the two layers of soft tissue together.

90. The method of claim 89 wherein said member comprises a hollow tube.

91. The method of claim 90 wherein the forming step results in a rivet-like anchor.

92. A method of securing two tissues together comprising:

forming an opening extending through the two tissues,

delivering a material, in a flowable state, to the opening, and

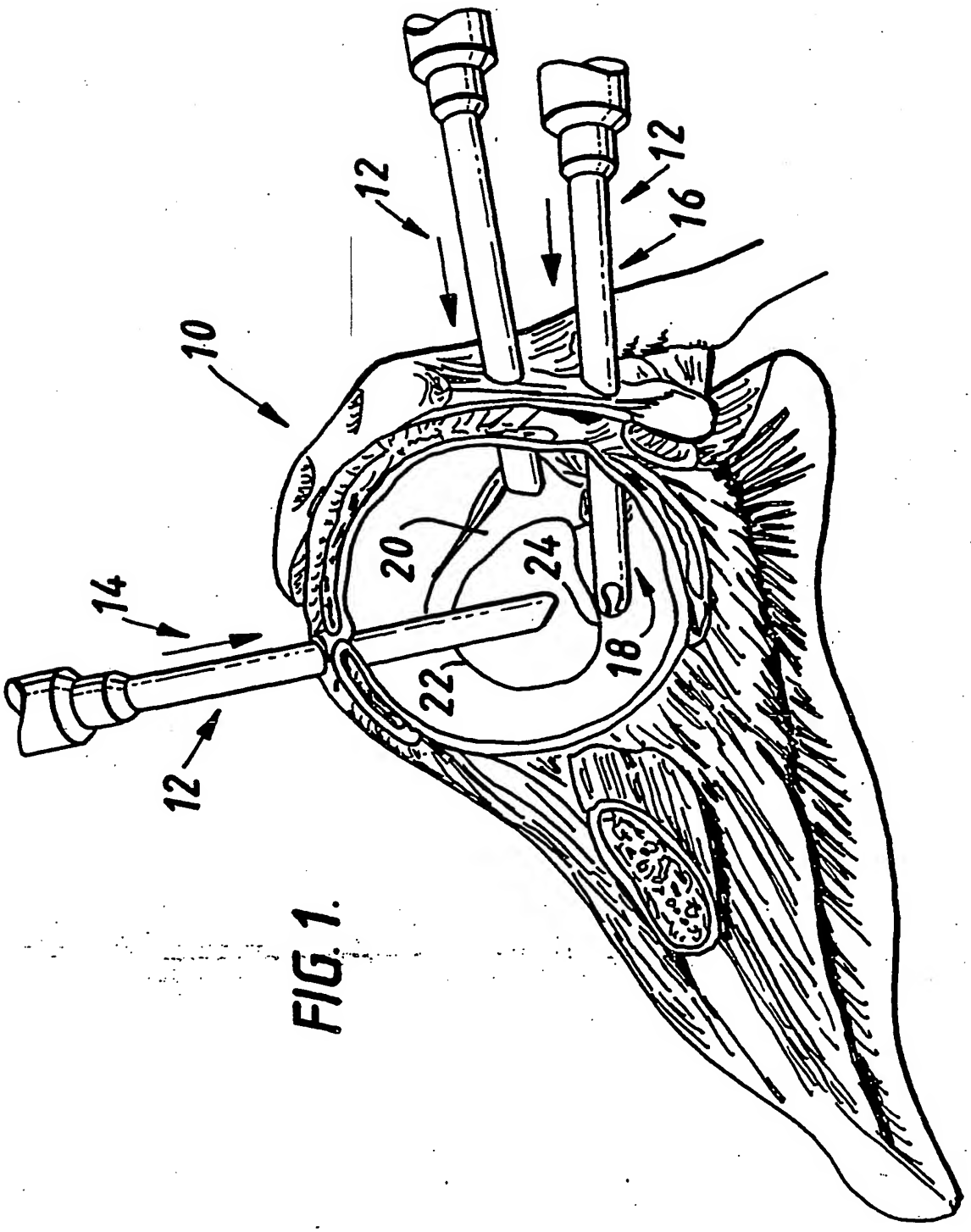


FIG. 1.

FIG. 2H.

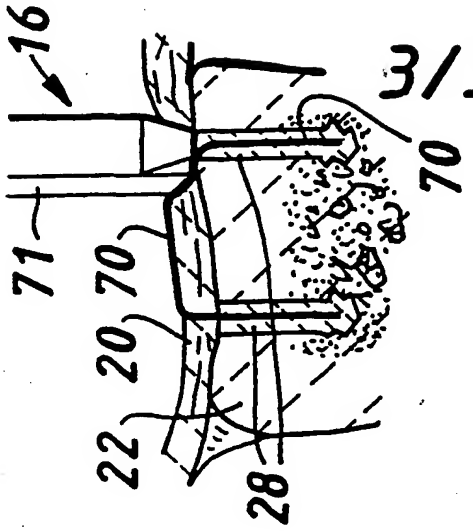


FIG. 2G.

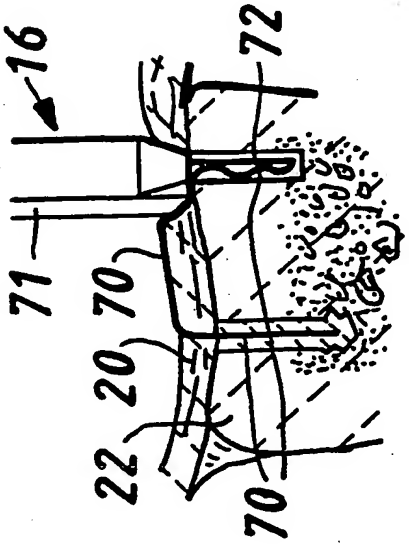


FIG. 2F.

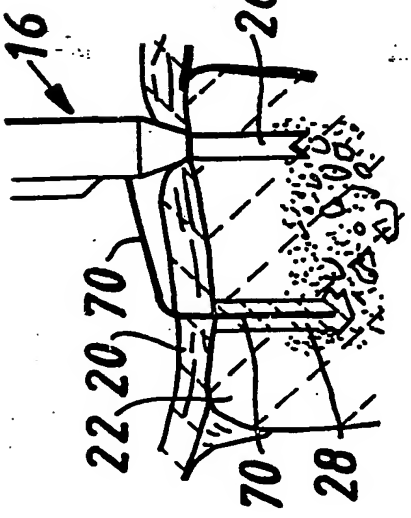


FIG. 2J.

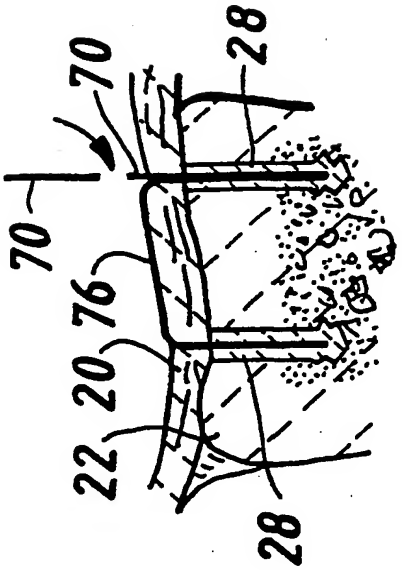
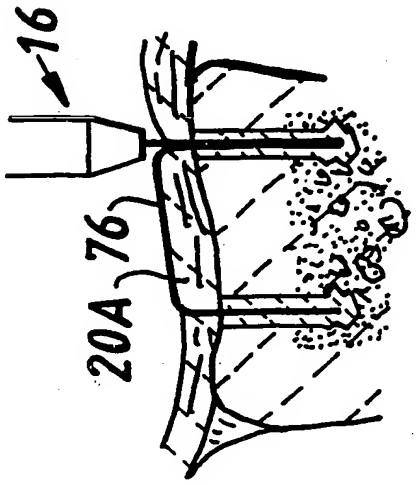


FIG. 2I.



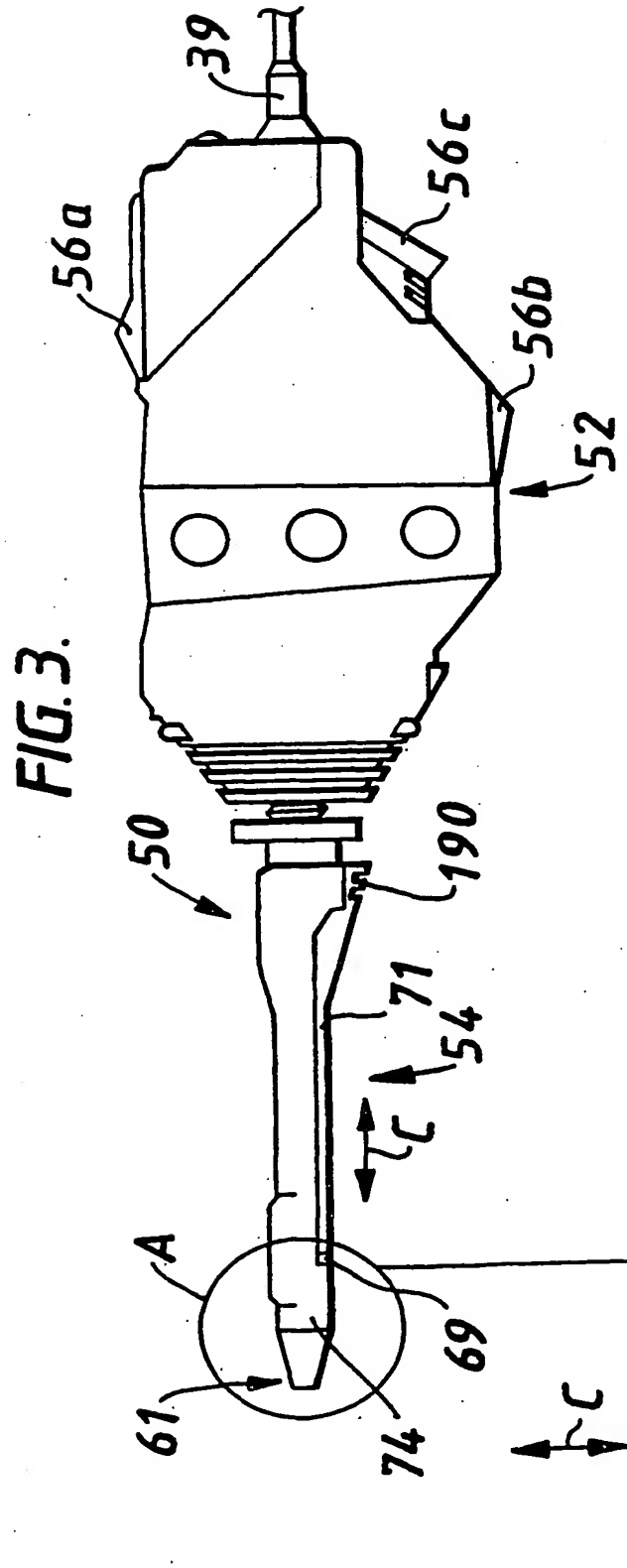


FIG.3.

FIG.3A.

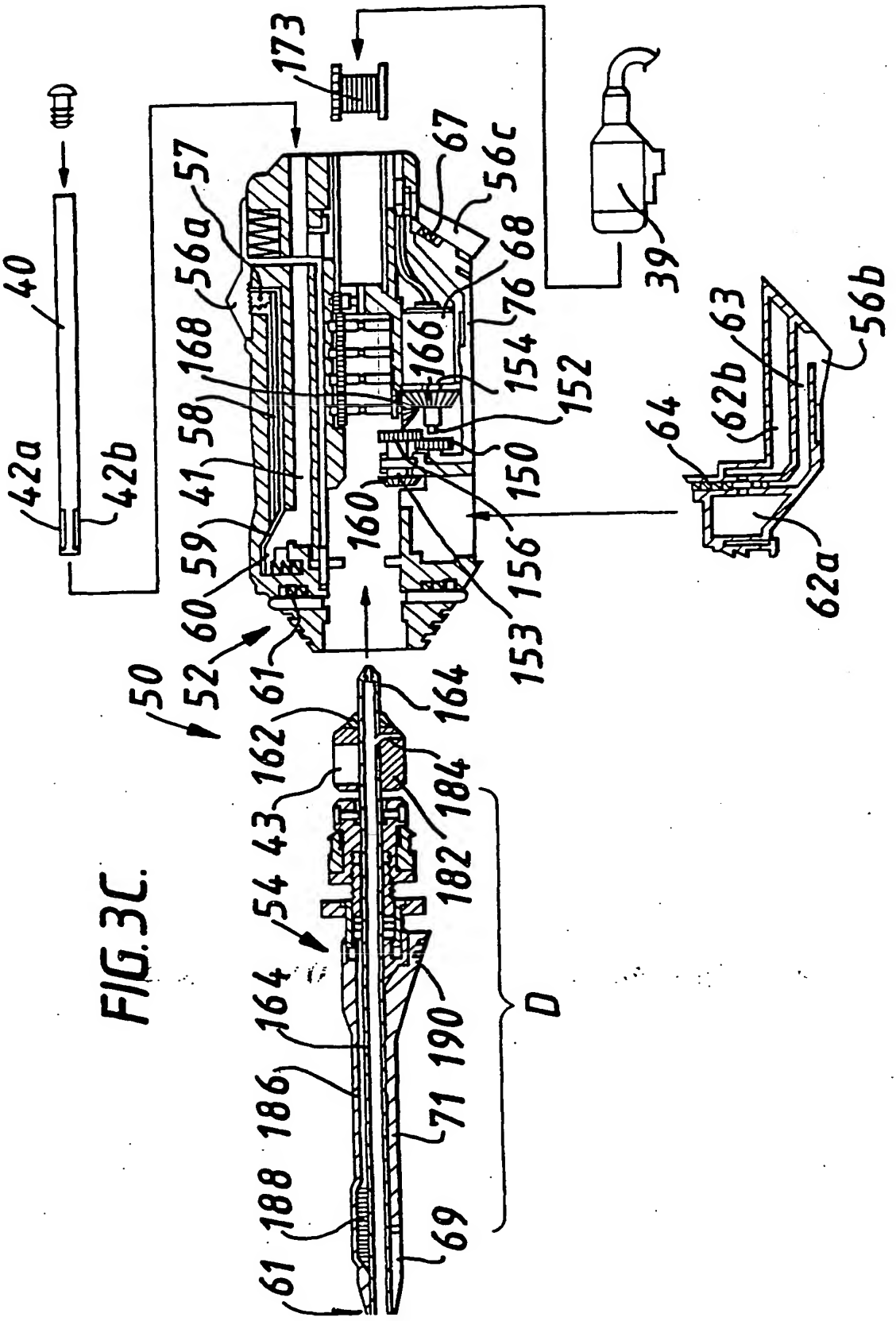


FIG. 3C.

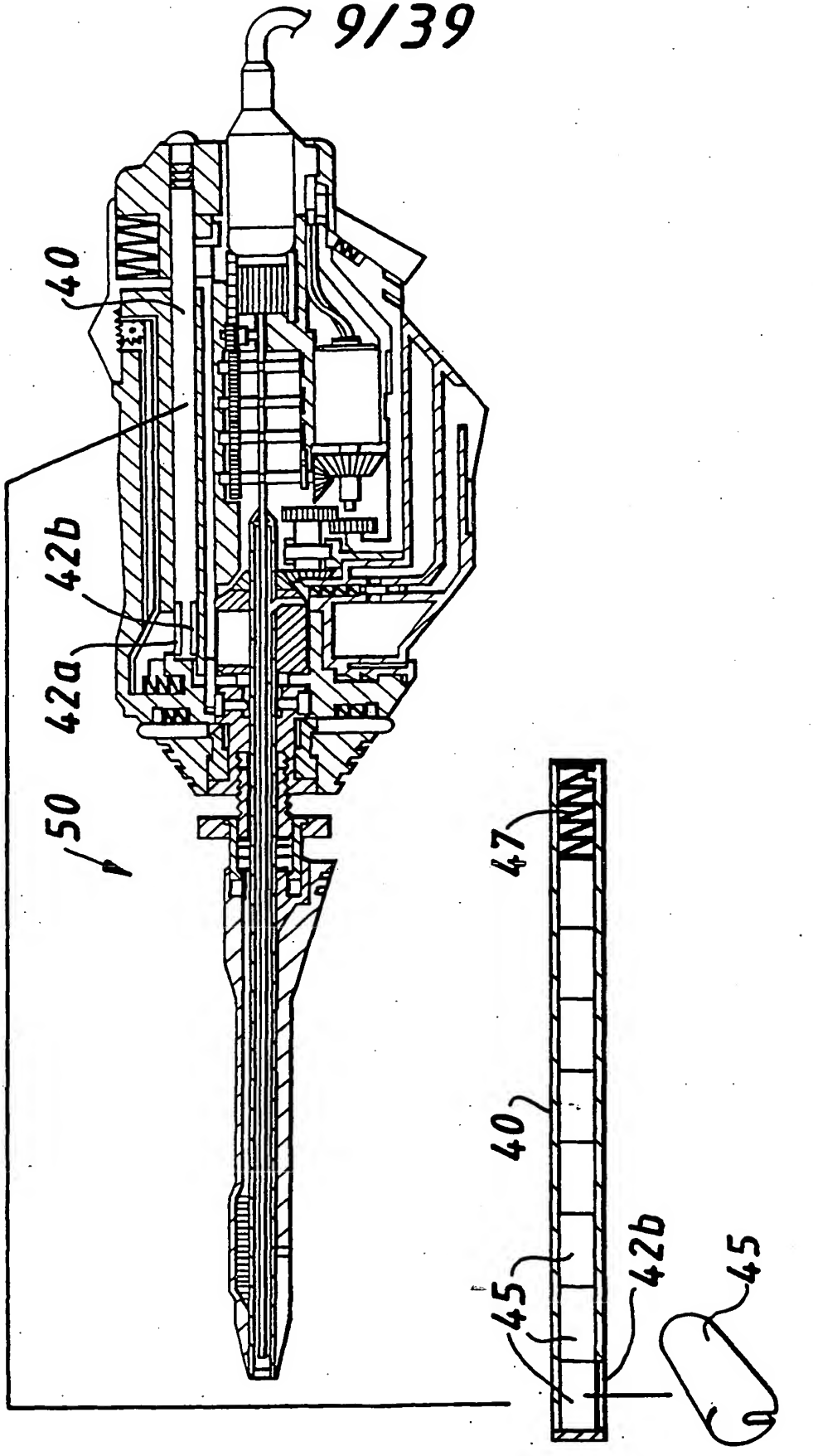


FIG. 3E.

FIG. 4C.

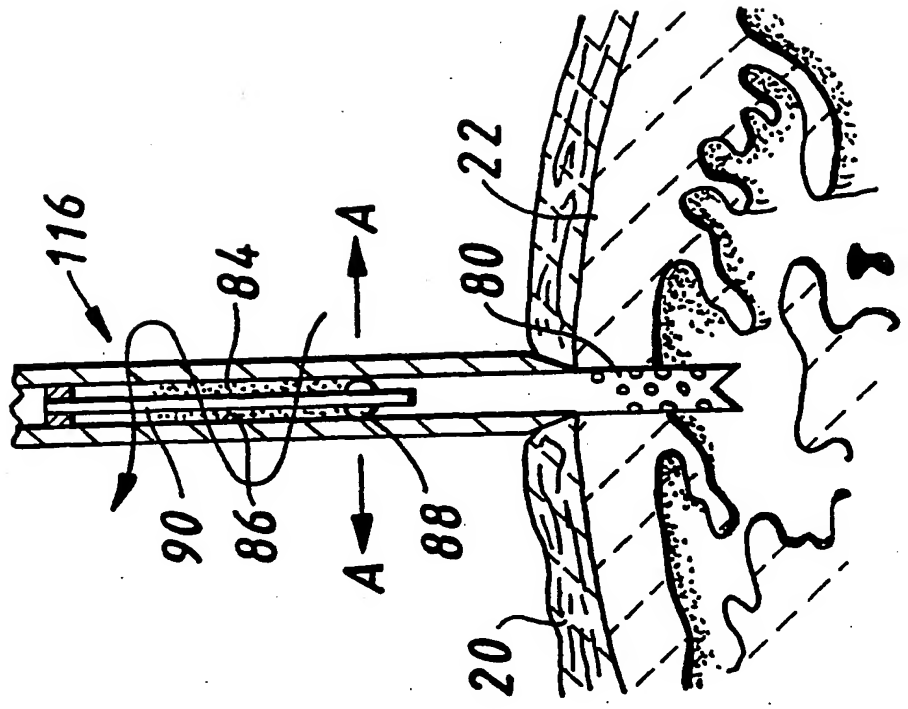


FIG. 4B.

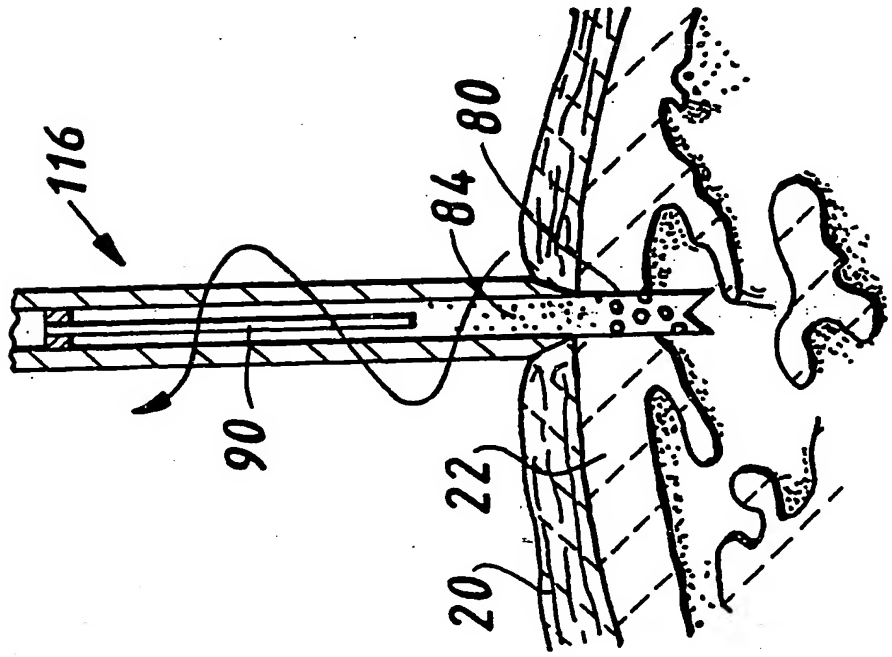


FIG.4G.

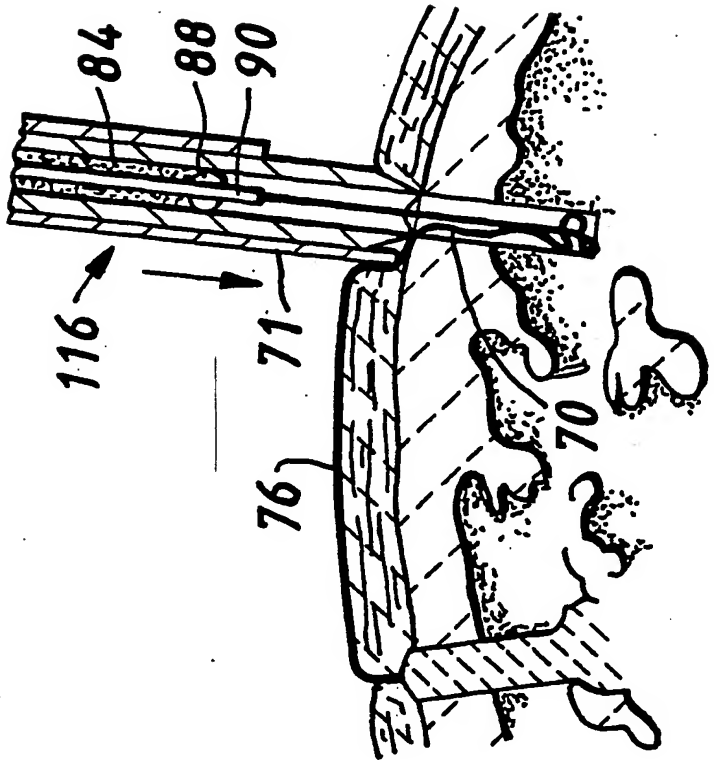


FIG.4F.

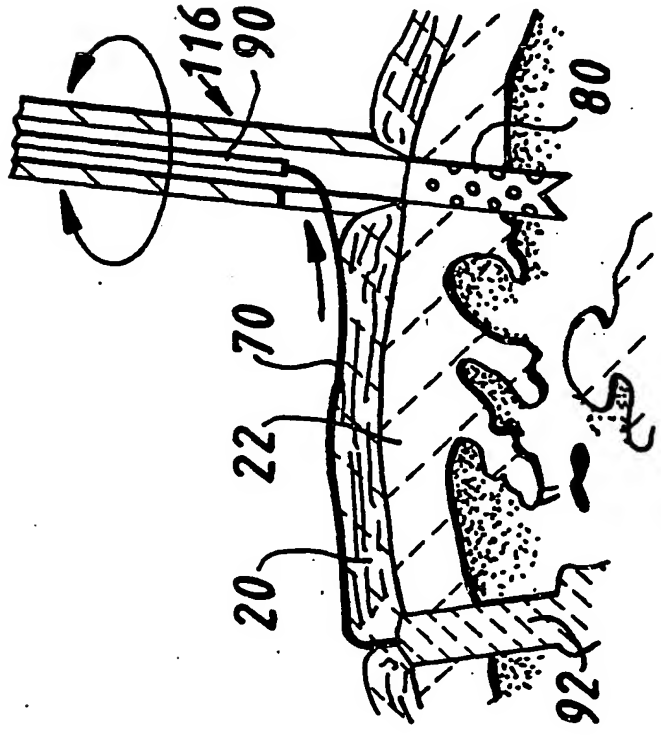


FIG. 4 J.

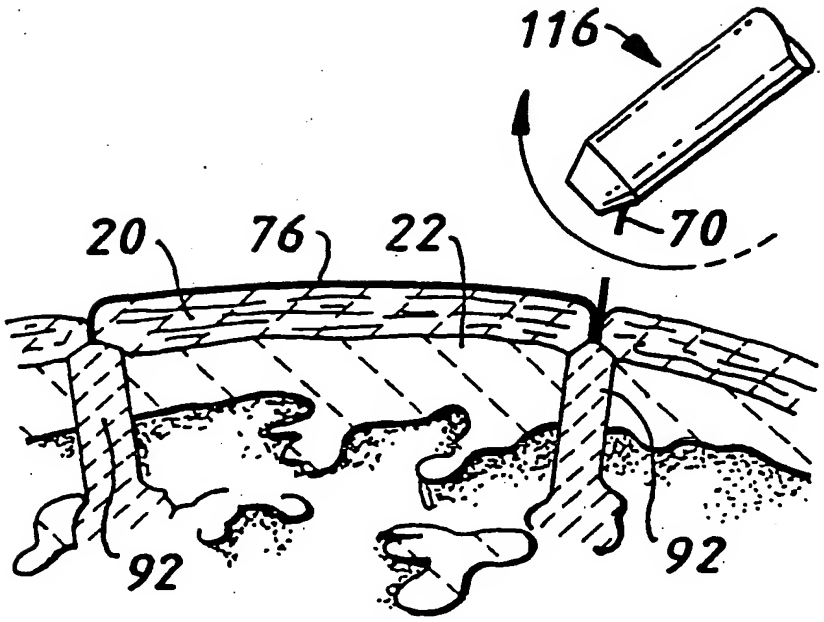


FIG. 5C.

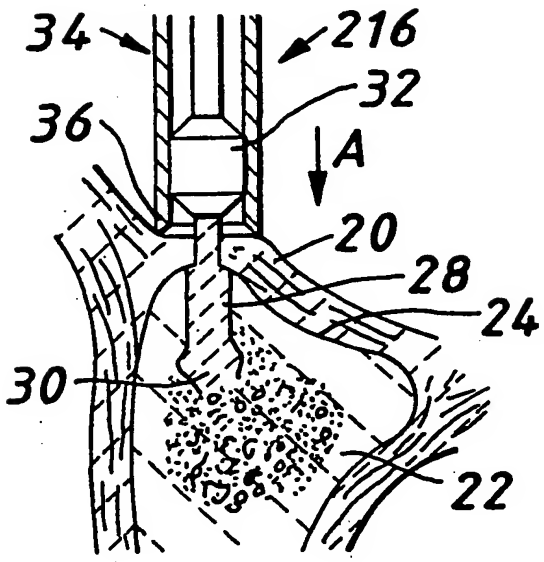


FIG. 5D.

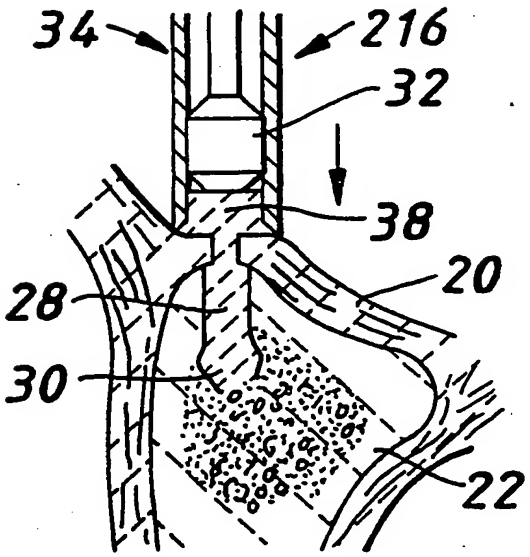


FIG. 5E.

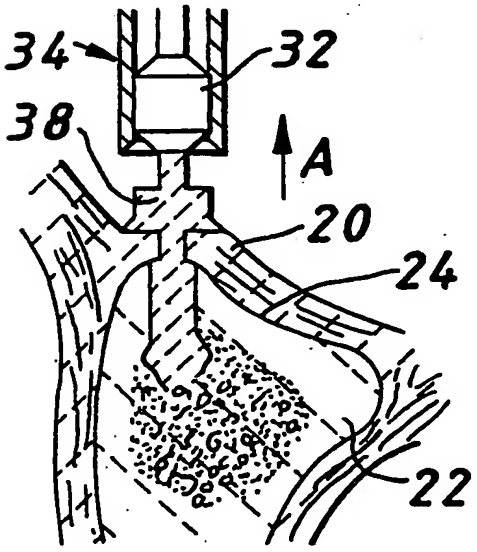
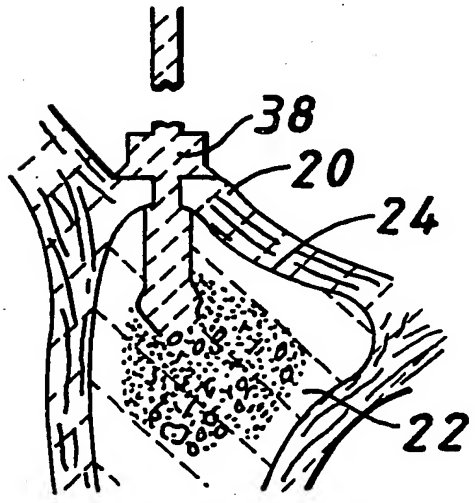


FIG. 5F.



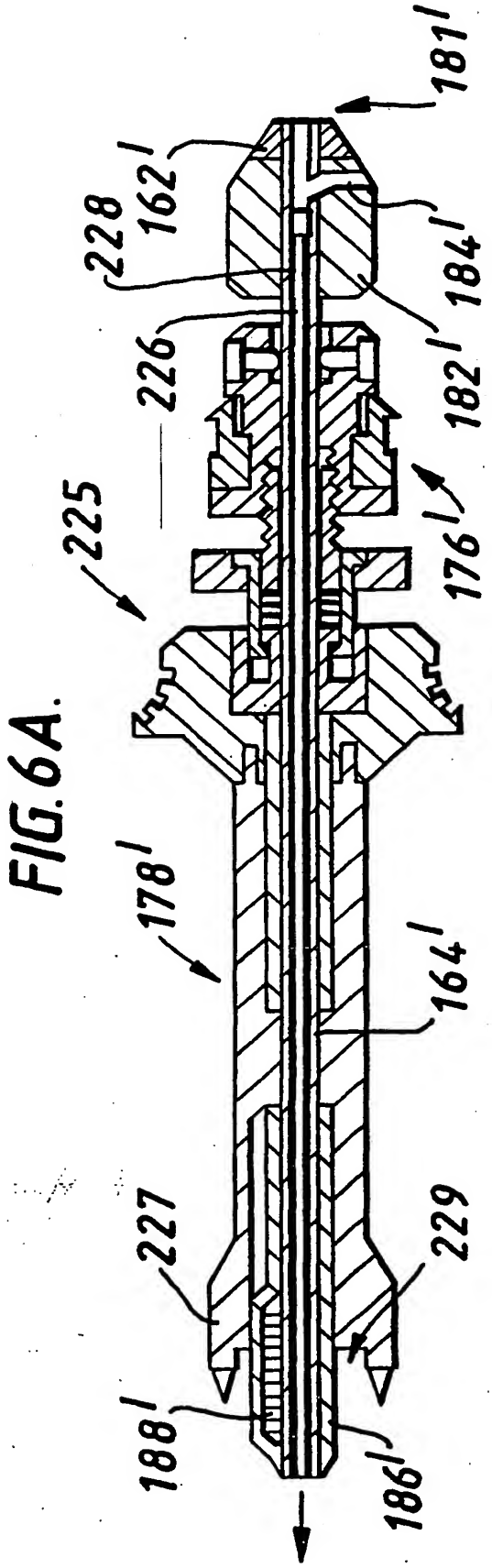


FIG. 6A.

FIG. 8.

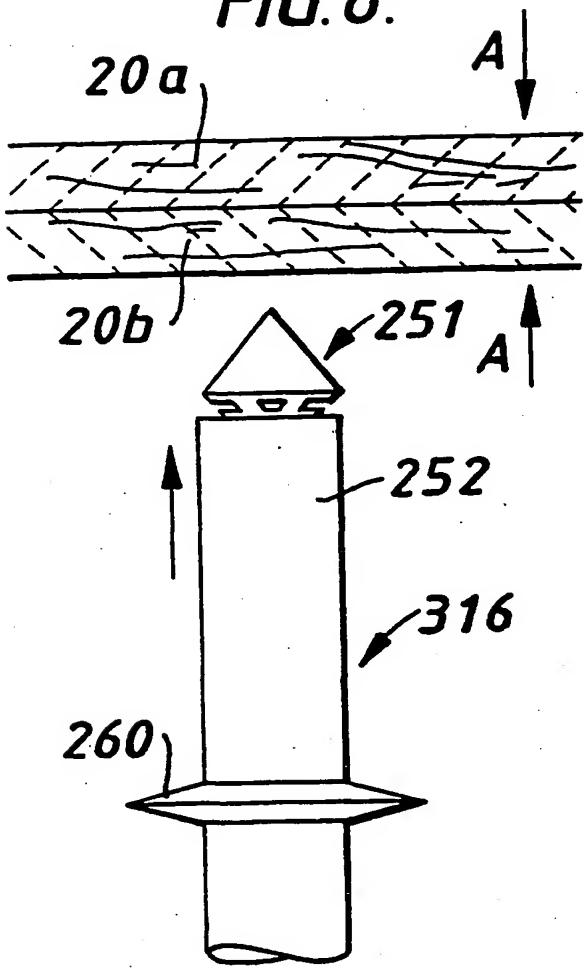
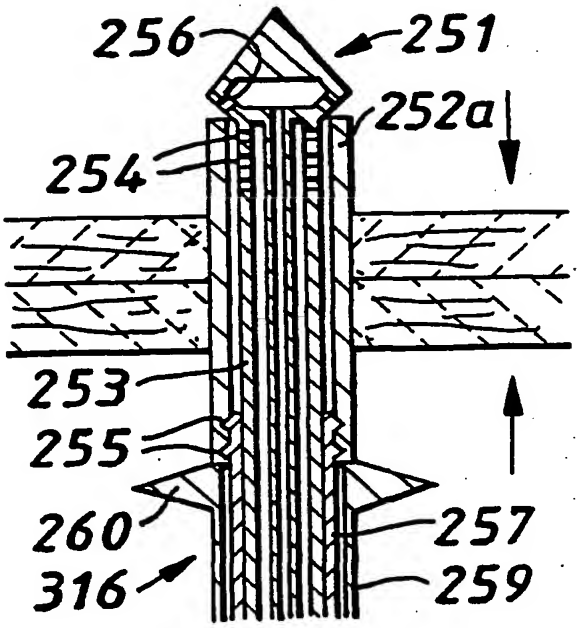


FIG. 8A.



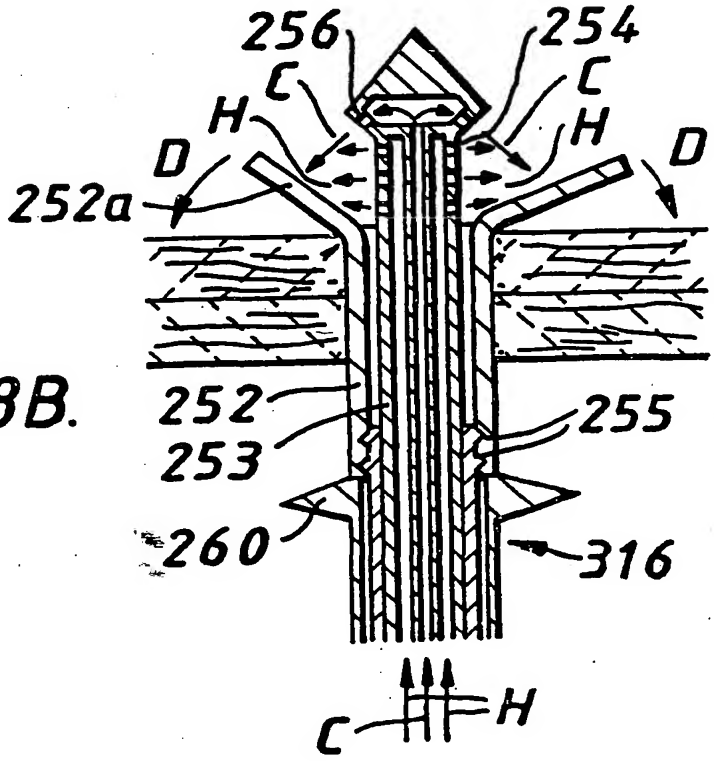


FIG. 8B.

FIG.9.

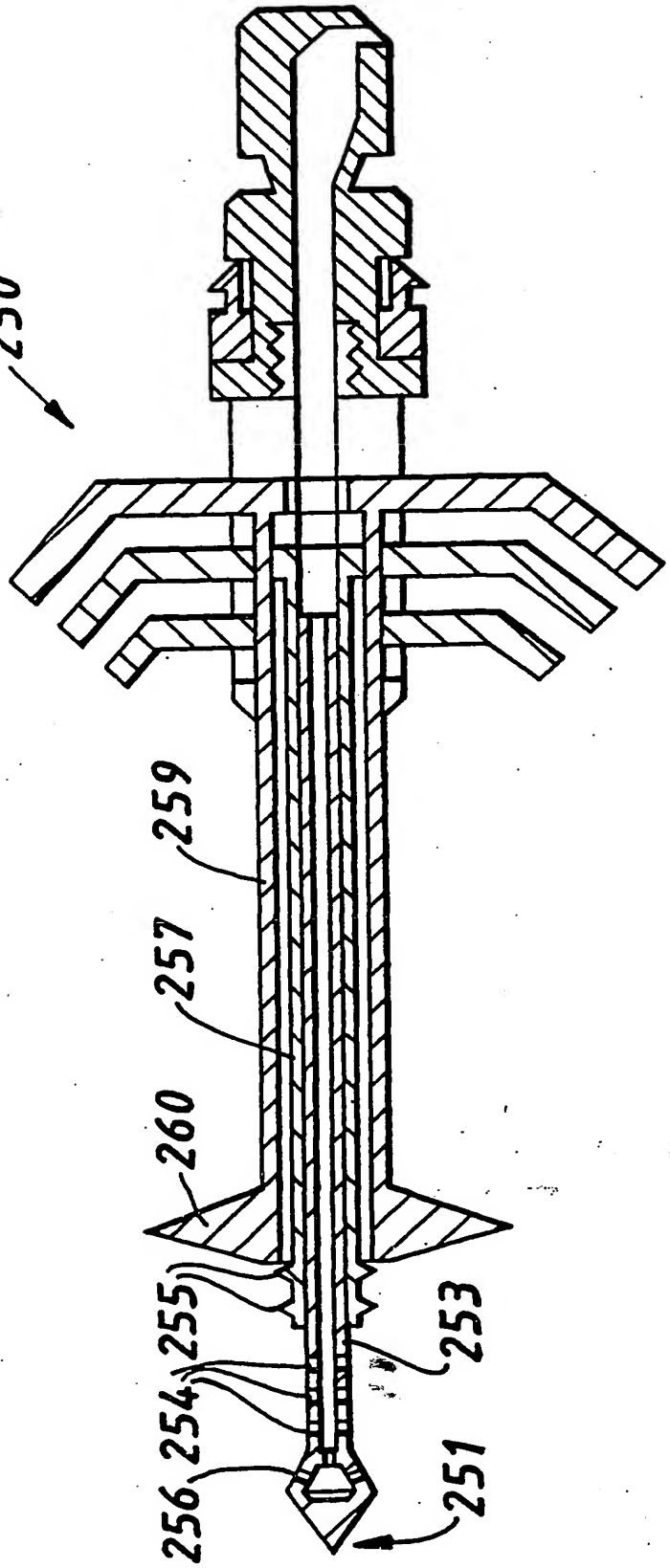


FIG.10C.

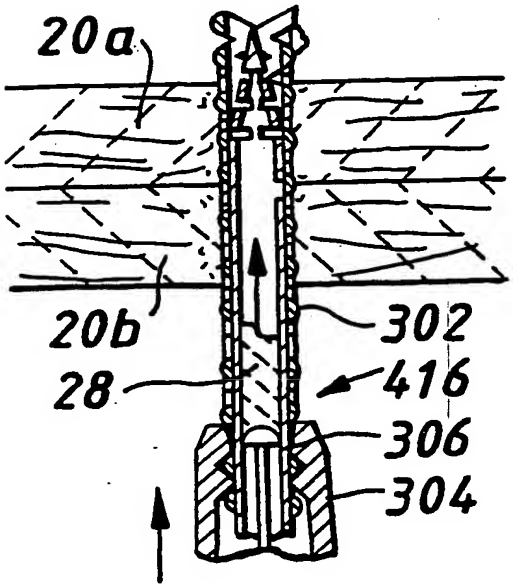


FIG.10D.

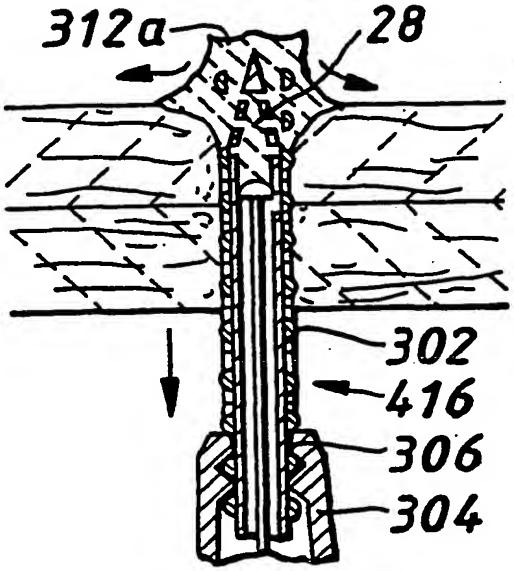
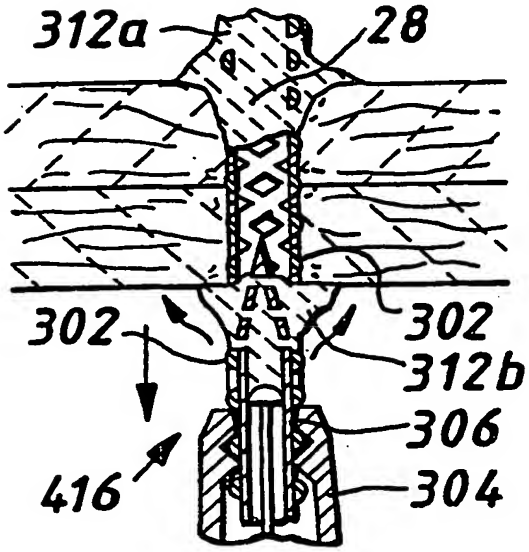


FIG.10E.



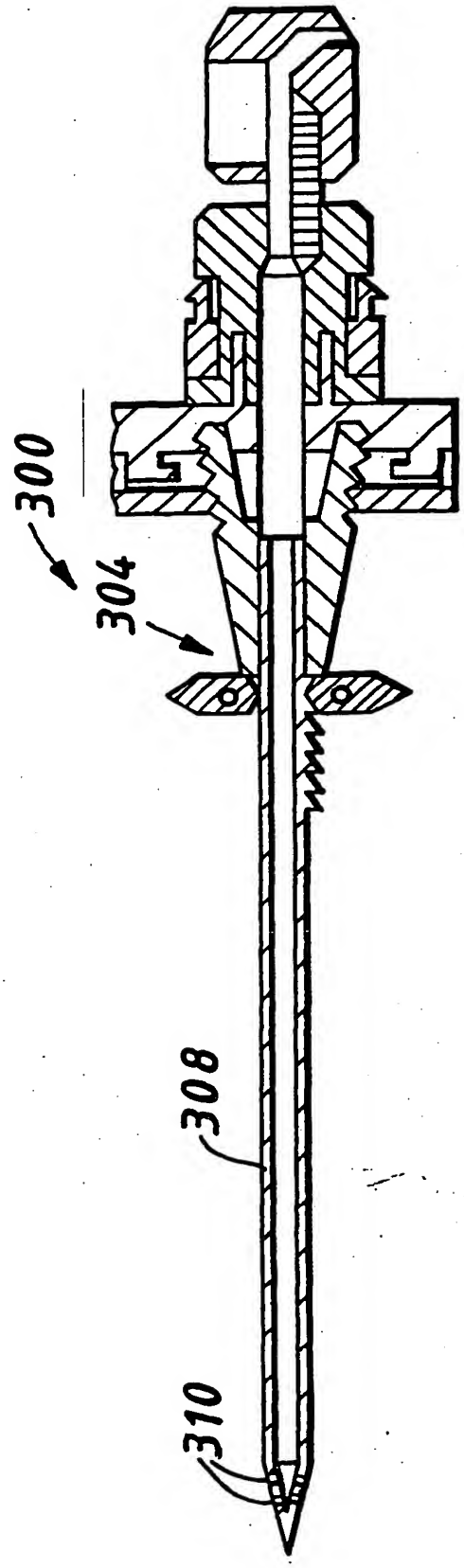


FIG.11.

FIG.12D.

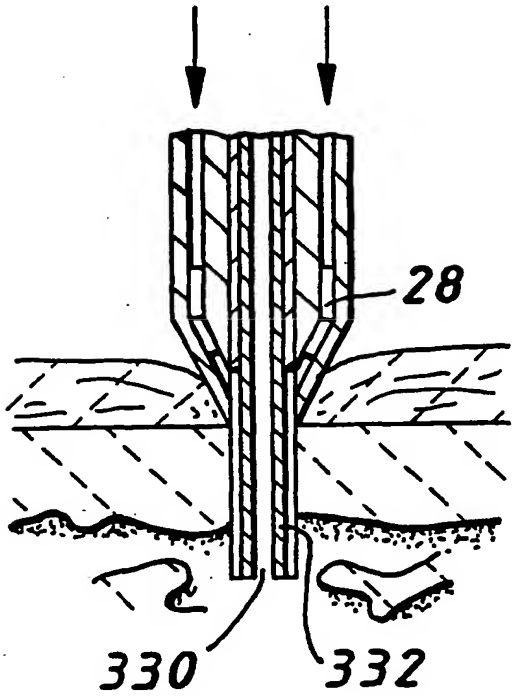


FIG.12E.

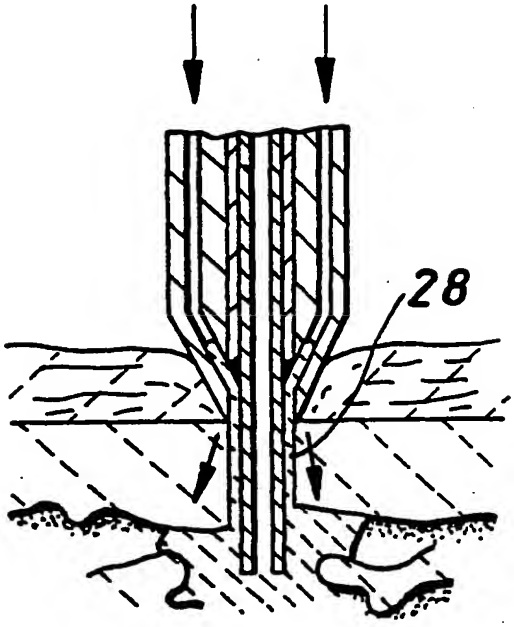


FIG.12F.

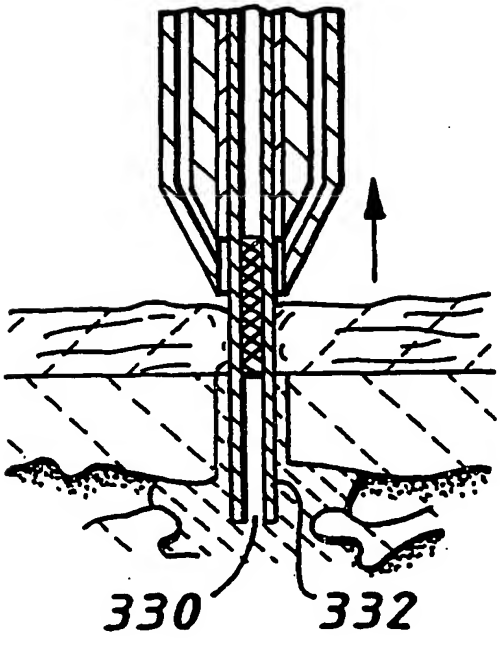


FIG.12G.

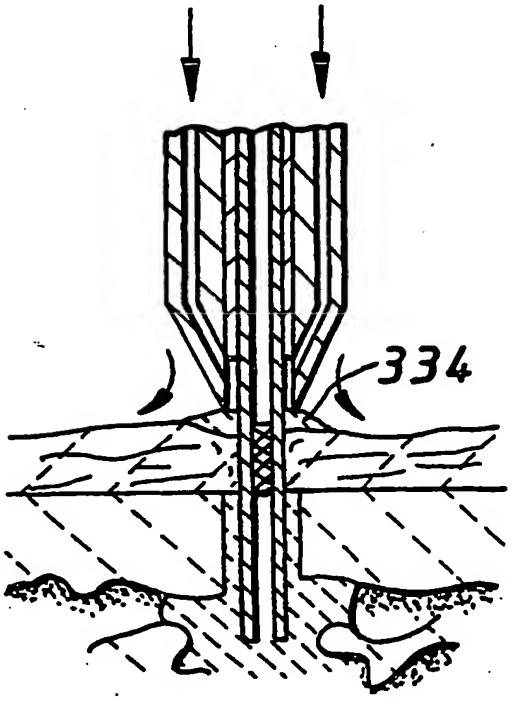


FIG.13. 31/39

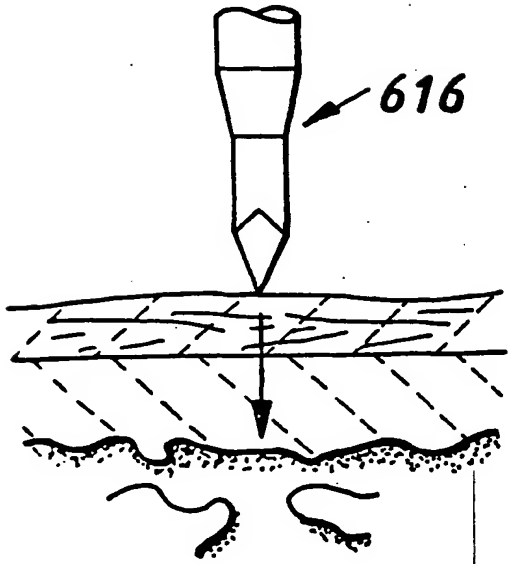


FIG.13A.

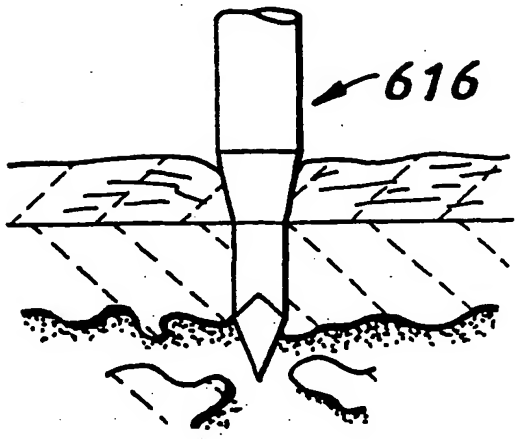


FIG.13B.

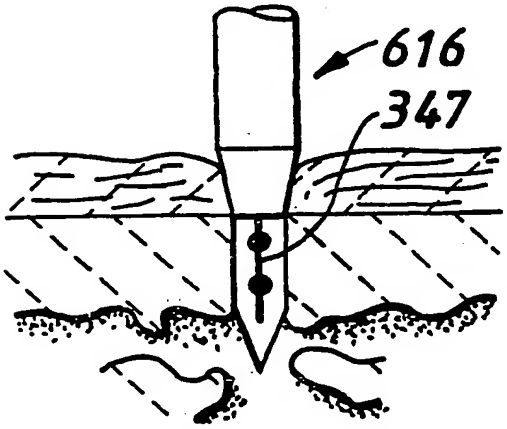


FIG.13C.

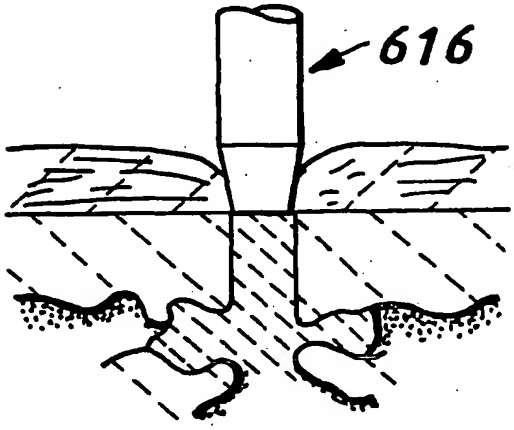


FIG.13D.

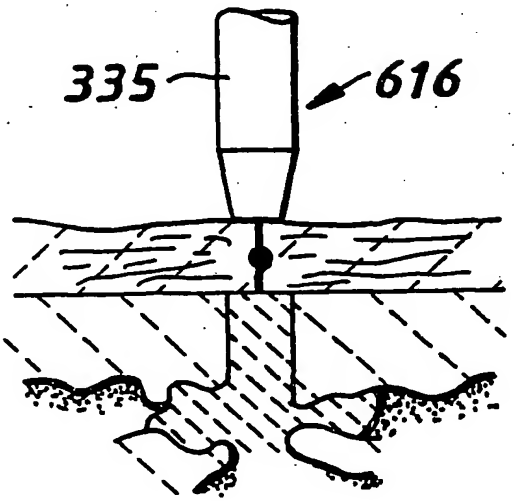


FIG.13G.

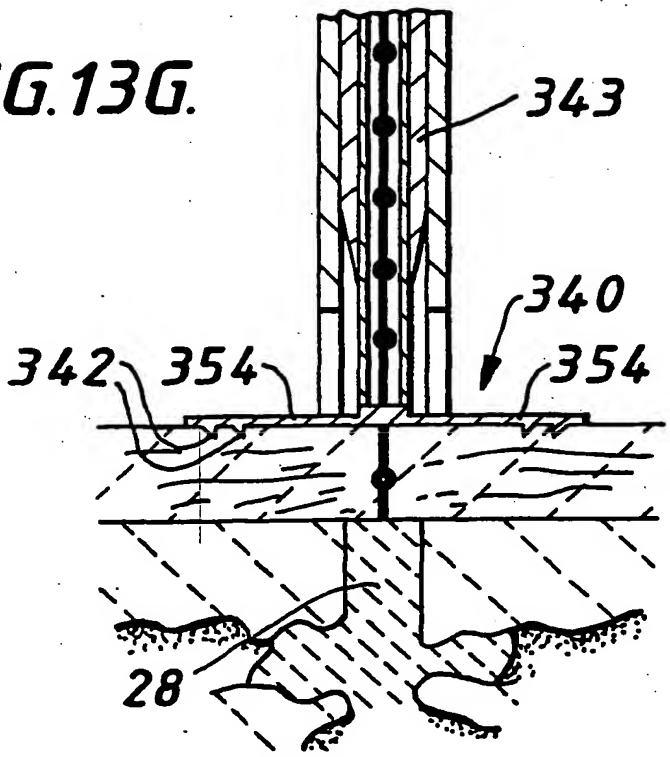


FIG.13H.

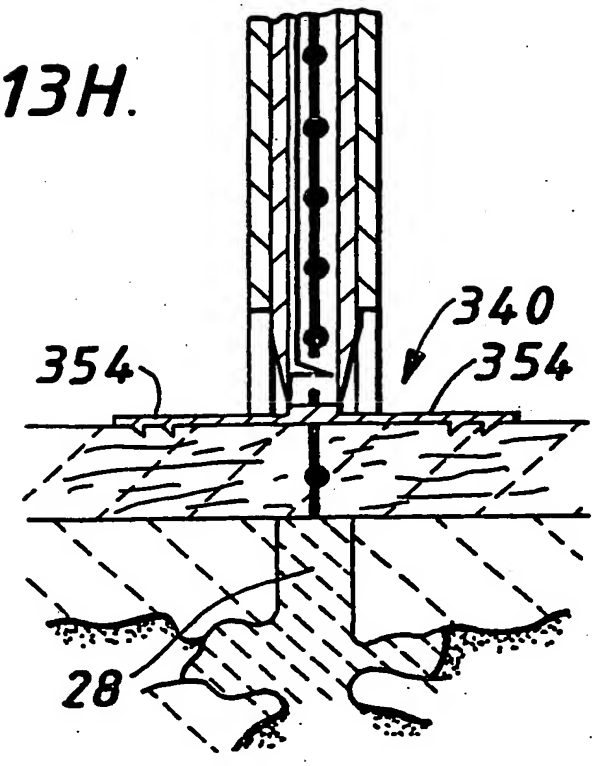


FIG.14.

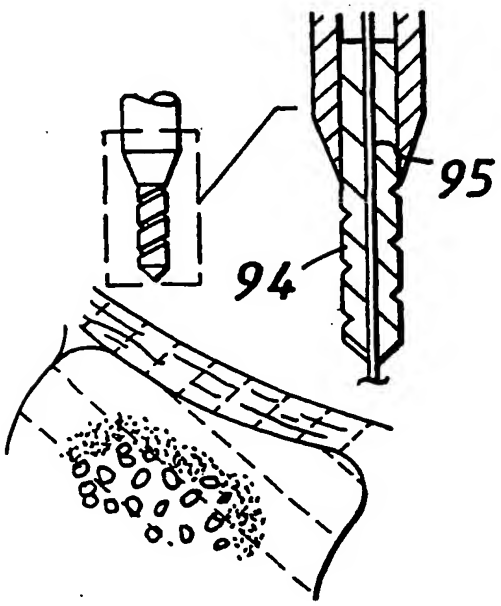


FIG.14A.

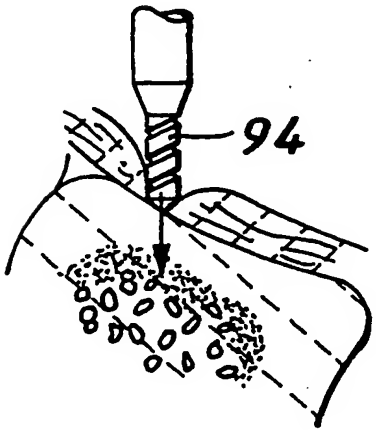


FIG.14B.

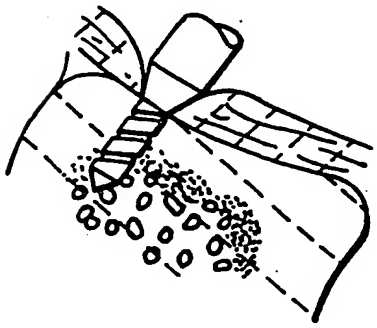


FIG.14C.

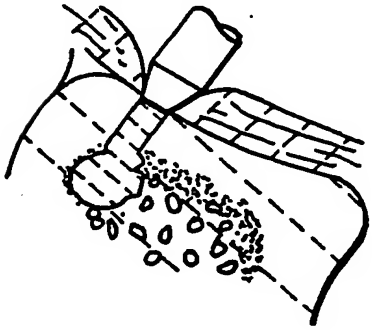


FIG.14D.

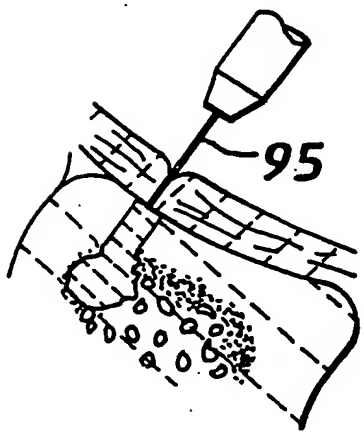


FIG. 17.

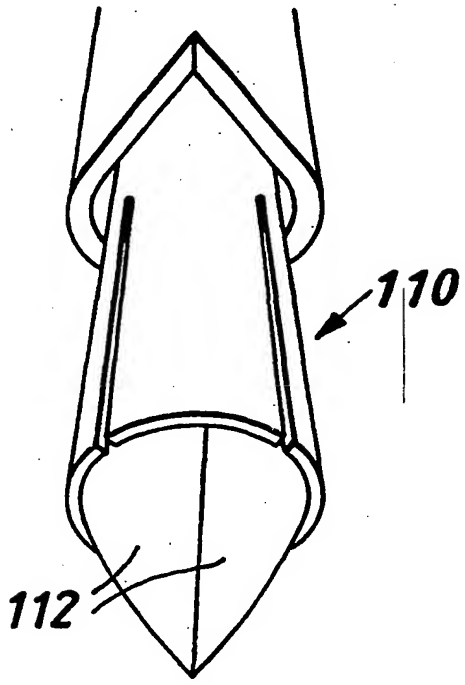


FIG. 17A.

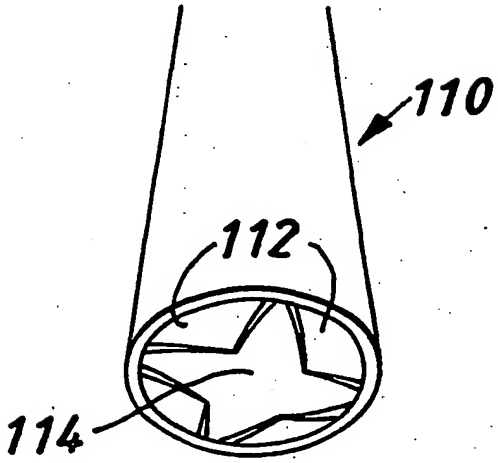


FIG. 18.

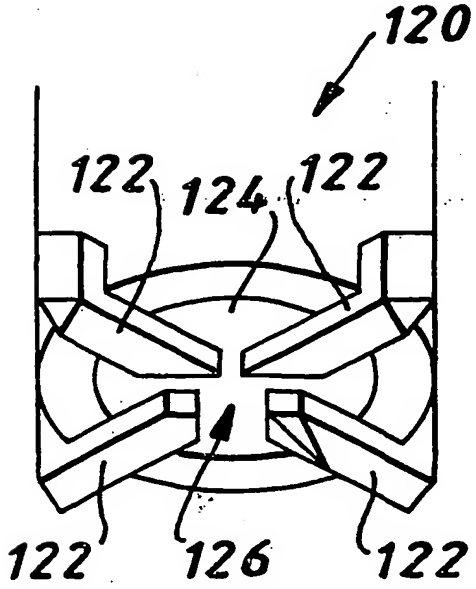


FIG. 18A.

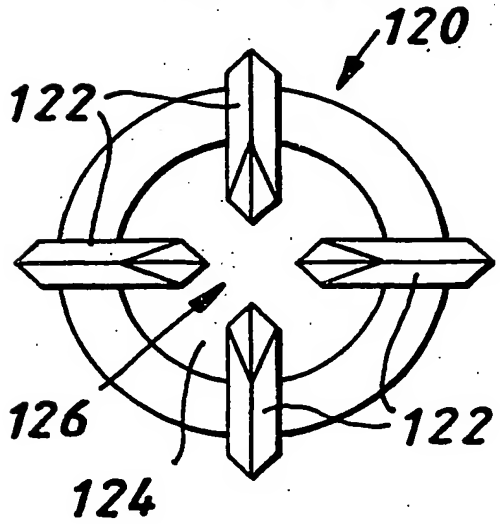


FIG.21.

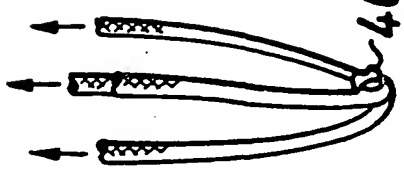


FIG.21A.

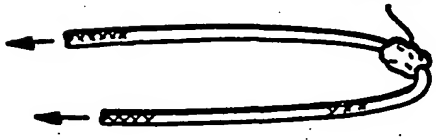


FIG.21B

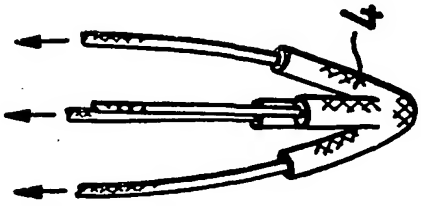


FIG.21C.

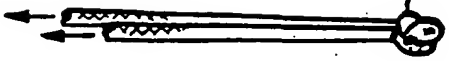


FIG.21D.

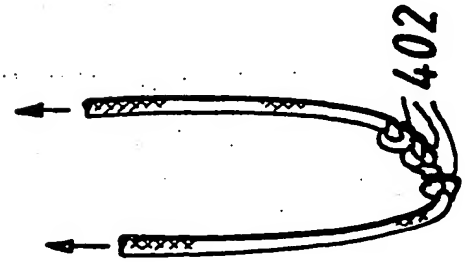


FIG.21E.

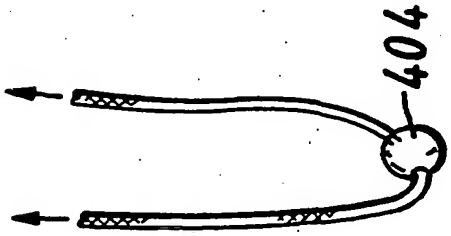


FIG.21F.

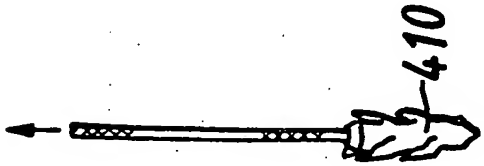
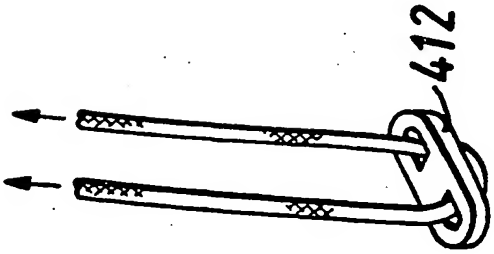


FIG.21G.



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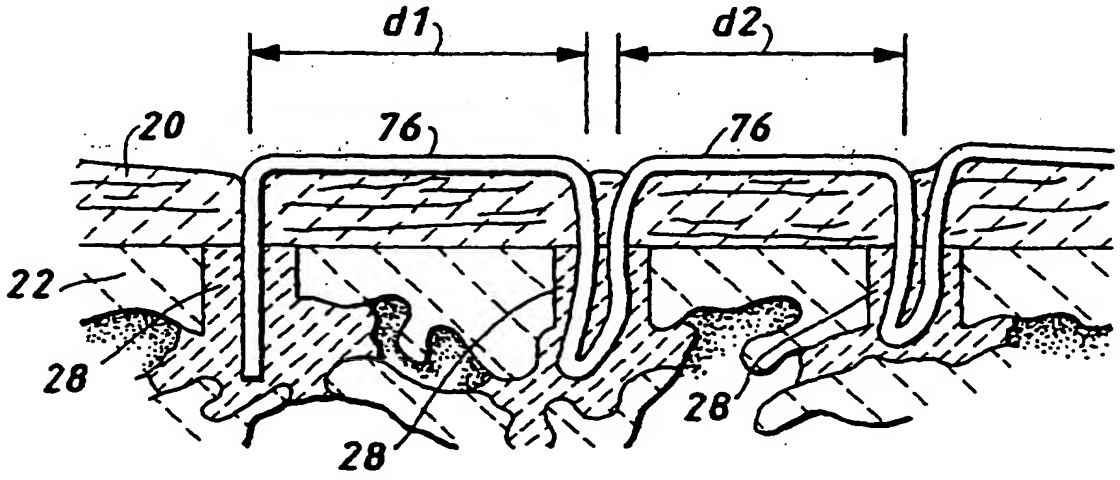

(57) Abstract: Surgical instruments and methods are provided. In one aspect, a method of securing a fixation device within an opening in a tissue is provided, including delivering a material in a flowable state to said opening, and changing the state of the material so that the material forms an interference fit that secures the fixation device in the opening.

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INTERNATIONAL SEARCH REPORT

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